Seat No.: _____ Enrolment No. _____

PARUL UNIVERSITY

FACULY OF PHARMACY

M.Pharm. Supplementary Examination , November - 2017

Year: 1 **Date: 08/11/2017**
Subject Code: 08204101 **Time: 10:00am to 1:00pm**
Subject Name: Research Methodology and Regulatory Ethics In Pharmacological Research **Total Marks: 75**

Instructions:
1. Figures to the right indicate maximum marks.
2. Make suitable assumptions wherever necessary.

Q.1 Essay Type Questions. (any 2 out of 3) (15 Mark Each) **(30)**

1. Explain in brief about 'Abstract and Discussion' section of scientific research paper. Enlist different reference styles used for preparing bibliography. Give examples for writing a reference of Research article, Review article, Book and Presentation using any two types of reference style.
2. What is literature review? Explain its importance. Discuss the various sources, Purpose, methods and use of literature survey in research.
3. Explain OECD guidelines for acute toxicity**.** Write on methods used for testing teratogenicity and carcinogenicity of drugs.

Q.2 Short Essay Type Questions. (any 5 out of 6) (5 Mark Each) **(25)**

1. Explain meaning of randomized, double blind, crossover clinical trial.
2. Describe the cost analysis for research project.
3. Define Factorial design. Describe the steps involved in doing the analysis of factorial design batches.
4. What is ANOVA? Explain the importance of using ANOVA in pharmaceutical research.
5. Describe how GCP guidelines historically evolved.
6. Define Trademark. Which different types of trademark can be registered as per Indian trademark law?

Q.3 Short Answers. (2 Mark Each) **(20)**

1. Explain types of research with examples.
2. Write the differences between research paper writing and thesis writing.
3. What is research proposal and research problem?
4. Write on different parts of a patent.
5. Give the elements of Informed Consent Form.
6. Write composition of institutional animal ethics Committee.
7. Explain responsibilities of sponsor and principal investigator
8. Discuss in brief formats of patent application.
9. What are Quality Audits and its benefits?
10. Enumerate the various techniques of documentation.